ISRCTN15108764 https://doi.org/10.1186/ISRCTN15108764

A comparison of sea-cucumber based gel to conventional hydrogels in wound healing

Submission date
11/01/2018

Recruitment status
No longer recruiting

Registration date
16/02/2018

Overall study status
Completed

Last Edited
15/10/2018

Condition category
Other

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Gamat (sea cucumber) has been widely used as a traditional medication/supplement for various ailments in South-east Asia, e.g. Malaysia, Indonesia, Thailand, Philippines and China. Gamat extracts contain many nutrients which may play a role in tissue repair, and they have been tested in rats and as a toothpaste in humans. However, to date, there have been no studies on human wounds. The aim of this study is to assess the effectiveness of Gamat gel in comparison with hydrogel in the treatment of skin graft donor sites.

Who can participate?
Patients with partial thickness wounds created as an after effect of skin graft harvesting

What does the study involve?
Both gels are applied to the patient simultaneously on the same wound divided into two areas. The duration of treatment is 10-14 days with follow up at day 21, then at 6 to 9 weeks. The effect is judged as which wound heals more on a specific day. Pain tolerance, itch tolerance, and scar quality are also assessed on both wound surfaces.

What are the possible benefits and risks of participating?
The results could show whether Gamat gel heals human cutaneous wounds faster or better. The risks would be allergic reactions, but these have not been reported so far.

Where is the study run from?
Hospital Universiti Sains Malaysia (Malaysia)

When is the study starting and how long is it expected to run for?
August 2016 to September 2017

Who is funding the study?
Universiti Kebangsaan Malaysia (Malaysia)

Who is the main contact?
Dr Adzim Poh Yuen Wen

Contact information

Type(s)
Public

Contact name
Dr Adzim Poh Yuen Wen

ORCID ID
https://orcid.org/0000-0002-0903-6152

Contact details
A-3-3, Laman Baiduri,
Jalan SS12/1, Wangsa Baiduri
Subang Jaya
Malaysia
47500

Additional identifiers

Protocol serial number
USM/JEPeM/16060218

Study information

Scientific Title
A prospective case-control comparative study to evaluate the efficacy of Gamat gel in comparison with hydrogel in treatment of skin graft donor sites

Study objectives
Null hypothesis: There is a no significant difference in the rate of epithelialization between Gamat gel dressing and Duoderm® Hydroactive® Gel dressing on skin graft donor sites.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Local ethics board in Hospital Universiti Sains Malaysia (JEPeM), 21/11/2016, ref: USM/JEPeM /16060218

Study design
Single-center prospective single-blinded comparative study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Skin graft donor site wounds

Interventions
This is a prospective, single-blinded, comparative clinical trial involving patients in Hospital Universiti Sains Malaysia with partial thickness wounds which were created as an after effect of skin graft harvesting. Any patient requiring skin grafting and fulfilling the inclusion/exclusion criteria will be approached preoperatively for recruitment. Both gels (sea-cucumber based gel and Duoderm (r) gel) will be applied on the patient simultaneously on the same wound, which is geometrically divided into two areas correspondingly. The effect is judged as which wound epithelializes more on a specific day. Pain tolerance, itch tolerance, and scar quality are also assessed on both wound surfaces. Duration of treatment 10-14 days. Follow up at day 21, then at 6 to 9 weeks.

Intervention Type
Other

Primary outcome(s)
Wound epithelialization, assessed by clinical judgment and calculated as percent of surface of wound epithelialized at day 10, 14 and 21 after intervention

Key secondary outcome(s))
1. Pain and pruritus assessed with visual analogue scale at day 10, 14 and 21
2. Scar quality assessed with modified Vancouver scar scale (MVSS) at follow up (week 6 to 9)

Completion date
04/09/2017

Eligibility

Key inclusion criteria
1. All patients with partial thickness wounds after split-skin graft harvesting
2. This thickness is at 0.2 mm (0.008 inch); harvested with a specified dermatome
3. Skin-graft donors > 25cm2 wide
4. Consented patients
5. Patients compliant to the treatment protocol

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Sex
All

Key exclusion criteria

1. Accidental full thickness harvesting
2. Non-compliant patient, causing dressing to dislodge
3. Patients with history of allergy to seafood/ sea cucumber
4. Patients with uncontrolled diabetes mellitus, on steroid medications or who are immunocompromised
5. Pregnancy
6. Patient with skin pathology (eczema etc)

Date of first enrolment
29/12/2016

Date of final enrolment
03/07/2017

Locations

Countries of recruitment
Malaysia

Study participating centre
Hospital Universiti Sains Malaysia
Department of Reconstructive Sciences
Kubang Kerian, Kelantan
Malaysia
16150

Sponsor information

Organisation
Hospital Universiti Sains Malaysia

ROR
https://ror.org/0090j2029

Funder(s)

Funder type
University/education

Funder Name
Universiti Kebangsaan Malaysia

Alternative Name(s)
Universiti Kebangsaan Malaysia (UKM), Universiti Kebangsaan Malaysia (UKM), Malaysia, ukminsta, Universiti Kebangsaan Malaysia - UKM, Universiti Kebangsaan Malaysia (Malaysia), University Kebangsaan (Malaysia), UKM

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Malaysia

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Adzim Poh Yuen Wen. A copy of the raw data has been submitted to the Medical Sciences Studies Centre (or Pusat Pengajian Sains Perubatan [PPSP]) of Hospital Universiti Sains Malaysia. All patients were assigned a coded number to protect anonymity.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/12/2018		Yes	No